



Attorney Docket: 128.004

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Irving M Fishman
Type or Print Name

Irving M Fishman
Signature

11/23, 2005
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Confirmation No.
9170

Applicant : Frieze, et al
Appl. No. : 10/070,621
Filed : Mar. 5, 2002
FOR : FILTERED GAS PLASMA
STERILIZATION CONTAINER
WITH IMPROVED
CIRCULATION

Art Unit: 1744
Examiner: Krisanne Jastrzab

Docket No. : 128.004
Customer No. :

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF MARCIA FRIEZE

Sir:

I, Marcia Frieze, residing at 45 Berkery Place, Alpine, NJ 07620, hereby declare and say as follows:

1. I graduated from Brooklyn College in 1967, having received a Bachelor of Arts degree in Sociology and Anthropology.
2. In 1970, I graduated from Columbia University, receiving a Master of Science degree in Social Work.
3. For one year, 1979-1980, I was employed at Piedmont Technical College in the position of Instructor.
4. From then until 1970-1982, I was employed at Montefiore, Columbia Presbyterian Psychiatric Institute, Kaiser Permanente (CA), and Family Support Center in Salt Lake City UT as a clinical social worker.
5. From then until 1994, I was employed as a Vice President at Dimedics Inc managing a mobile CT scanning service.
6. Since 1992, I have been Vice President and then CEO of Case Medical Inc., Ridgefield NJ, the owner of the above-identified application.
7. I am an author in at least 11 articles set forth below.
 - "Sterilization Containers" – Infection Control Today – 11/00;
 - "Container System Effectiveness" – SSM – 2/01;
 - "To Flash or Not to Flash" – Managing Infection Control – 5/01;
 - "Sterilization Solutions for the New Millennium" – Managing Infection Control – 6/01;
 - "A Case for Inventory Control" – Infection Control Today - 7/01;
 - "Instruments Missing in Action" – Infection Control Today – 12/01;
 - "Bio-terrorism: The Invisible Enemy" – SSM – 2/02;
 - "Making A Case For Properly Processing & Storing Endoscopes" – EndoNurse – 3/02;
 - "Challenges Impacting the Reprocessing of Reusable Medical Devices" – Managing Infection Control – 9/03;

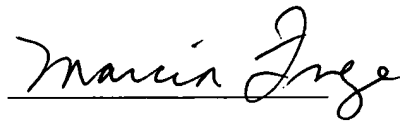
"Assuming Responsibility with Sustainable Solutions" – Managing Infection Control – 1 –2003; and

"Flash Sterilization: A Case Study" – Managing Infection Control – 11/03.

9. I am an inventor in the above-identified application and an inventor in several other patents dealing with sterilization equipment.
10. I am familiar with the present application and the last office action in the above-identified case and give this declaration in support of Applicants arguments in favor of patentability.
11. In the Interview of November 15, 2005, the Examiner had requested that the Applicant provide a Declaration with respect to the critical nature of the anodic layer thickness limitation in the claims. That limitation is a maximum of 0.5 mils and a minimum of 0.2 mils.
12. The upper limit (0.5 mils) was based on a risk analysis of the gas plasma process. Too thick an anodized layer inhibits sterilization. In fact, a competitor's product, having a layer of 0.6 mils (a mere 0.1 mils thicker than the claimed maximum) failed an evaluation for STERRAD. In contrast, the devices of the invention having not greater than 0.5 mils, and preferably 0.25 to 0.35 mils, all pass evaluation for STERRAD. The thicker the anodic coating, the more absorbent the surface is of the sterilant so that insufficient sterilant reaches the surfaces intended to be sterilized. This is especially critical in gas plasma sterilization.
13. The lower limit was chosen because 0.2 mils to 0.6 mils meets the specification for corrosion resistance using MIL-A-8625 (military specification).

14. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this patent application and any patent issuing thereon.

Respectfully submitted,

A handwritten signature in cursive script, reading "Marcia Frieze", is written over a horizontal line.

Marcia Frieze

November 22, 2005